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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,034	01/03/2001	Jouko Savolainen	81757.0029	9155

26021 7590 07/15/2003
HOGAN & HARTSON L.L.P.
500 S. GRAND AVENUE
SUITE 1900
LOS ANGELES, CA 90071-2611

EXAMINER

MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,034

Applicant(s)

SAVOLAINEN, JOUKO

Examiner

Abdel A. Mohamed

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

ACKNOWLEDGMENT TO AMENDMENT, RESPONSE, STATUS OF THE APPLICATION AND CLAIMS

1. The amendment and remarks filed 5/5/03 are acknowledged, entered and considered. In view of Applicant's request claims 1-12 have been amended and claims 13-18 have been added. Thus, claims 1-18 are now pending in the application. The objections to the specification and abstract and the rejections under 35 U.S.C. 112, first paragraph and 35 U.S.C. 112, second paragraph are withdrawn in view of Applicant's amendment, remarks and substitution of the originally filed specification with the amended specification filed 5/5/03. However, the rejection under 35 U.S.C. 103(a) over the prior art of record is maintained.

CLAIMS REJECTION-35 U.S.C. § 103(a)

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 and newly submitted claims 13-18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/22907 taken with Petruccelli et al., (J. Agric. Food Chem., Vol. 43, pp. 2001-2006, 1995).

The instantly claimed invention as amended in independent claim 1 is directed to a method for modification and isolation of proteins from whey or soy comprising a) providing a protein selected from a group consisting of whey and soy proteins; b) providing a reagent that forms sulfite ions; c) mixing the protein with the reagent under a condition to sulfonate the protein without using an oxidizing agent and to obtain a mixture containing a sulfonated protein; d) precipitating the sulfonated protein at an acid pH to form a precipitated sulfonated protein and a soluble protein; and e) recovering the precipitated sulfonated protein or the soluble sulfonated protein.

Similarly, WO 95/22907 teaches a method for modification and isolation of protein from whey comprising a) whey or a concentrate thereof, a reagent which forms sulfite ions, and an oxidant are brought into contact in order to sulfonate, b) the sulfonated and oxidized whey protein is precipitated out from the whey or concentrate thereof at an acid pH, and c) the precipitated sulfonated and oxidized whey protein is recovered from the product mixture and possibly subjected to an after-treatment (See e.g., page 1 lines 4-14). The precipitation step b) preferably carried out by using a pH value of approximately 2.5-6.5, and most preferably a pH value of 3.0-5.0. After the pH adjustment of step b), the temperature is adjusted to be sufficiently high, preferably within the range 25-55°C, most preferably within the range 30-50°C. The protein content of the whey concentrate is 2-7% and the dry weight of the concentrate is 11-12%. The sulfonation in a) employs the sulfite as Na_2HSO_3 , Na_2SO_5 or Na_2SO_3 and is used at the concentration in an amount of 0.02-0.20 M, preferably 0.05-0.1 M (See e.g., page 9, lines 30 to page 10, lines 8; page 11, lines 34 to page 12 lines 26; claims 1-2, 4 and 7-8).

The reference of WO 95/22907 differs from claims 1-12 and newly submitted claims 13-18 in not teaching the sulfonation of the whey protein without using oxidizing

agent (i.e., omitting the oxidation step in the claimed process). Although, on pages 5-6, the primary reference discloses the advantages and disadvantages of using oxidative sulfitolysis with the purpose of isolating proteins from whey wherein the oxidant being oxygen and the catalyst a Cu^{++} ion as CuCO_3 . Based on oxidative sulfitolysis, the result either did not aim at providing a method of isolation but only a method of modifying certain properties, or the method is so difficult to exploit on an industrial scale that it cannot be implemented. Thus, the primary reference clearly suggests that the use of oxidizing agent would decrease the yield of the product desired in large-scale production. Further, the secondary reference of Petruccelli et al., teach the partial reduction of disulfide bonds of soy protein isolates in which the addition of catalyst (Cu) and oxygen showed a similar effect in the sulfitolysis of soy proteins with Na_2SO_3 . (See e.g., abstract). On page 2006, the reference clearly shows that in the presence of a catalyst (Cu) and/or an oxidizing agent (O_2), the AB-11S subunits is not completely reduced, probably because the reducing agent is unable to reach all SS bonds. Reduction of soy protein isolates with sodium sulfite affects different subunits according to the reaction conditions employed; namely, mostly AB dimers are reduced if urea is used, whereas if Cu or O_2 is employed, mainly components other than AB-11S undergo change. The reference continues by stating that to obtain complete sulfitolysis, both urea and C or O_2 are required. The reference concludes by stating that the addition of a catalyst (Cu) and oxidizing agent (O_2) affects similarly the sulfitolysis of soy proteins with Na_2SO_3 ; the simultaneous presence of both agents is not required. Thus, clearly showing that without using an oxidizing agent that one of ordinary skill in the art would be able to obtain complete sulfitolysis in a method for modification and isolation of proteins from whey or soy.

Therefore, the employment of a method for modification and isolation of a protein such as whey or soy protein by sulfonating the protein with or without using an oxidizing agent and then precipitating the sulfonated protein at acidic pH and recovering thereof in the manner claimed in claims 1-12 and newly submitted claims 13-18 appears to be obvious as taught by the combined teachings of the prior art at the time the invention was made because the secondary reference clearly taught the simultaneous presence of both agents (i.e., catalyst and oxidizing agent) is not required. Hence, one of ordinary skill in the art would have been motivated to modify the method for modification and isolation of proteins from whey which requires oxidizing agent taught by the primary reference to substitute into a method for modification and isolation of proteins from whey without using oxidizing agent as taught or suggested by the secondary reference since the secondary reference has shown as discussed above that without using an oxidizing agent that one of ordinary skill in the art would be able to obtain complete sulfitolysis in a method for modification and isolation of proteins from whey or soy. Thus, it would have been obvious to one of ordinary skill in the art to apply the teachings of the secondary reference to the primary reference because such features are known and suggested in the art, as seen in the secondary reference, and including such features into the method of the primary reference would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof.

Therefore, in view of the above and in view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated at the time the invention was made to employ a method for modification and isolation of a protein such as whey or soy protein by sulfonating the protein without using an oxidizing agent and then precipitating the sulfonated protein at acidic pH and recovering thereof in the

manner claimed in claims 1-12 and newly submitted claims 13-18; which fall within the scope of the combined teachings of the prior art method would have been prima facie obvious from said prior art disclosure to a person of ordinary skill in the art because in the absence of sufficient objective factual evidence or unexpected results to the contrary, Applicant's claims are directed to optimization of an "art recognized variable" which is well within the purview of one of ordinary skill in the art, In re Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

ARGUMENTS ARE NOT PERSUASIVE

3. The rejection of claims 1-12 and newly submitted claims 13-18 under 35 U.S.C. 103(a) as being unpatentable over WO 95/22907 taken with Petruccelli et al., (J. Agric. Food Chem., Vol. 43, pp. 2001-2006, 1995).

Applicant's arguments filed 5/5/03 have been fully considered but they are not persuasive. Applicant has argued that none of the cited references either singularly or in combination teach or suggest a method of sulfonation of whey or soy proteins without using oxidizing agent is unpersuasive. Contrary to Applicant's arguments, the Examiner has clearly indicated as discussed above that the primary reference of WO 95/22907 differs from claims 1-12 and newly submitted claims 13-18 in not teaching the sulfonation of the whey protein without using oxidizing agent (i.e., omitting the oxidation step in the claimed process). Although, on pages 5-6, the primary reference discloses the advantages and disadvantages of using oxidative sulfitolysis with the purpose of isolating proteins from whey wherein the oxidant being oxygen and the catalyst a Cu^{++} ion as CuCO_3 . Based on oxidative sulfitolysis, the result either did not aim at providing a method of isolation but only a method of modifying certain properties, or the method is so difficult to exploit on an industrial scale that it cannot be implemented. Thus, the

primary reference clearly suggests that the use of oxidizing agent would decrease the yield of the product desired in large-scale production. Further, the secondary reference of Petruccelli et al., teach the partial reduction of disulfide bonds of soy protein isolates in which the addition of catalyst (Cu) and oxygen showed a similar effect in the sulfitolysis of soy proteins with Na_2SO_3 . (See e.g., abstract). On page 2006, the reference clearly shows that in the presence of a catalyst (Cu) and/or an oxidizing agent (O_2), the AB-11S subunits is not completely reduced, probably because the reducing agent is unable to reach all SS bonds. Reduction of soy protein isolates with sodium sulfite affects different subunits according to the reaction conditions employed; namely, mostly AB dimers are reduced if urea is used, whereas if Cu or O_2 is employed, mainly components other than AB-11S undergo change. The reference continues by stating that to obtain complete sulfitolysis, both urea and C or O_2 are required. The reference concludes by stating that the addition of a catalyst (Cu) and oxidizing agent (O_2) affects similarly the sulfitolysis of soy proteins with Na_2SO_3 ; the simultaneous presence of both agents is not required. Thus, clearly showing that without using an oxidizing agent that one of ordinary skill in the art would be able to obtain complete sulfitolysis in a method for modification and isolation of proteins from whey or soy.

With respect to Applicant's arguments on page 11, last paragraph on the remarks filed 5/5/03 that Petruccelli (the secondary reference) concludes that the presence of oxidizing agent is needed to achieve complete sulfitolysis (abstract and page 2006, second paragraph under Conclusions) is not persuasive. Although, in the abstract Petruccelli states that to achieve a complete sulfitolysis, the presence of a denaturing and an oxidizing agent were needed; however, contrary to Applicant's arguments and as discussed in the above paragraph, the reference clearly states on page 2006, third paragraph under Conclusions that this isolate, (i.e., soy protein isolate) in spite of

having a high percentage of reduced SS bonds, only has 20% reduction of the AB subunit of glycin. Treatment with Na_2SO_3 lead to only 10 % reduction, whereas a concentration 100 times higher increases that percentage to 40 % (at 7 h and in the absence of either denaturing or oxidizing agents). Thus, clearly showing and/or motivating that without using an oxidizing agent that one of ordinary skill in the art would be able to obtain complete sulfitolysis in a method for modification and isolation of proteins from whey or soy. Further, amended claim 11 does not exclude and/or omit the oxidation step in the claimed process as argued by Applicant.

Therefore, in view of the above and in view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated at the time the invention was made to employ a method for modification and isolation of a protein such as whey or soy protein by sulfonating the protein without using an oxidizing agent and then precipitating the sulfonated protein at acidic pH and recovering thereof in the manner claimed in claims 1-12 and newly submitted claims 13-18; which fall within the scope of the combined teachings of the prior art method would have been *prima facie* obvious from said prior art disclosure to a person of ordinary skill in the art because as held in host of cases including *Ex parte Harris*, 748 O.G. 586; *In re Rosselet*, 146 USPQ 183; *In re Burgess*, 149 USPQ 355 and as exemplified by *In re Betz*, "the test of obviousness is not express suggestion of the claimed invention in any and all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them".

In regard to Applicant's allegation that as shown in Examples 1-8, the method of the present invention unexpectedly allows precipitation of as much as 66 % of the protein by using non-oxidative sulfitolysis resulting in speeding up the process rendering it economically more profitable is unpersuasive because the results shown in Examples

1-7 of the primary reference is similar with Examples 1-8 disclosed in the instant specification. Further, on page 7, the primary reference clearly discloses concentration and/or precipitation of whey protein at 75 % by weight. Thus, for Applicant to show unexpected results as alleged, Applicant has to provide side by side comparison with unexpected results showing that there is patentable difference between the instant invention's method and the prior art method of modifying and isolating protein from whey or soy. However, Applicant is cautioned that this is not an invitation to prolong the prosecution of After Final rejection.

ACTION IS FINAL

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


CONCLUSION AND FUTURE CORRESPONDANCE

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

 Mohamed/AAM

July 12, 2003



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600